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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,366	05/16/2001	Richard A. Brauckman	TGXX-1005US	3214

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EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No.	Applicant(s)	
	09/858,366	BRAUCKMAN ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20-31 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20-31 and 33-35* is/are rejected.

7)☒ Claim(s) *22-24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This action is responsive to the amendment filed on 12/9/02.

Claim Objections

Claims 22-24 are objected to because of the following informalities.

In line 4 of claim 22, "body" should be "attachment" for clarity.

In line 2 of claim 23, "body" should be "attachment" for clarity.

In line 2 of claim 24, "body" should be "attachment" for clarity.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. (US 5,199,939).

Dake et al. disclose a catheter 10 for endoluminal radiation treatment having an elongated flexible, hollow body 12 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter (Figure 1, Figure 9, col. 2, lines 49-54, col. 3, lines 58-68 and col. 4, lines 1-8 and lines 34-36) wherein the radioactive means can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12 (col. 5, lines 19-22). Dake et al. also disclose that catheter 10 has stiffening elements "sufficient strength and flexibility" to navigate vasculature without crimping (col. 4, lines 9-16). Dake et al. further disclose that the radioactive means 14 provides from about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (col. 5, line 68 and col. 6, lines 1-5).

Dake et al. do not specifically disclose that the radioactive source 14 is placed onto body 12 by bonding.

It is well known that attachment of one material to the surface of another material requires proper bonding or adherence by ensuring sufficient bond strength to prevent subsequent separation of the materials. Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have placed a radioactive source onto body 12 of the catheter of Dake et al. wherein the radioactive source is attached by bonding with sufficient bond strength for proper adherence. Further, it would have been obvious to have provided a suitable amount of radioactive material in the radiation source 14 to obtain radioactivity of 0.5 microcuries to about 300 curies per centimeter length, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 3 and 4, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have bonded the radiation source to the inside surface of body 12, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 7.

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Hess (US 5,302,168).

Dake et al. do not disclose that catheter 10 is a balloon catheter wherein the radioactive source 14 is located on the expandable portion of the balloon. A balloon catheter is a well-known type of catheter.

Regarding claim 2, Hess teaches a device 10 for radiation treatment including a catheter with a balloon 36 with radioactive elements or source 38 attached to an exterior surface of balloon 36 (col. 3, lines 41-45, Figure 2 and Figure 4) wherein when the balloon 36 is expanded in the vicinity of the lesion or treatment site, the radioactive source 38 is forced into contact with the treatment site.

Regarding claim 5, Hess teaches an embodiment of device 10 including a retractable sheath (wire wound for radiation containment or shielding) or shield 24 that can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to

a treatment site such that a window cut-out 32 in radiation source 30 is opened to expose the treatment site to a radiation dose (col. 3, lines 26-40).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath as taught by Hess in the catheter 10 of Dake et al. for radiation containment or to have substituted catheter 10 of Dake et al. with a balloon catheter having a balloon 36 with radiation source elements 38 attached thereto as taught by Hess for forced contact of the radiation source with the treatment site.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Carden, Jr. (US 5,405,309).

Dake et al. do not disclose carrier-free palladium 103 as the radiation source.

Carden, Jr. teaches carrier-free palladium 103 (Pd-103) as a safe radiation source for therapeutic purposes (col. 1, lines 40-45, col. 4 and col. 5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free Pd-103 as the radiation source in the Dake et al.- Hess device for enhanced safety.

Claims 7, 8, 11, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Liprie (US 5,282,781).

Dake et al. disclose that the radioactive means is a plurality of cylindrical pellets 14 having a sufficiently small diameter to fit within the distal end or radioactive segment 30 of catheter body 12 (Figure 9 and col. 5, lines 18-24).

Dake et al. do not specifically disclose that the catheter body 12 provides access to the cavity housing the radioactive source.

Liprie teaches an assembly having a hollow tube or "catheter-like body" with a radioactive source 25 housed in a cavity in the distal end of tube 10 wherein a plug 27 is utilized for placement and containment of radioactive source 25 within the cavity (col. 5, lines 63-68, col. 6, lines 1-15 and lines 41-68, Figure 1, and col. 10, lines 21, 25-26, and lines 48-52).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of

the catheter body 12 of Dake et al. wherein a plug 27 is provided for placement and containment of radioactive source 25 as taught by Liprie. Although, Liprie does not specifically teach that plug 27 is removable after placement, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a removable plug 27 since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Further, it would have been obvious to have provided a suitable amount of radioactive material in the housing to obtain a radioactivity level of 0.5 microcuries to about 300 curies per centimeter length of the radioactive segment 30, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Liprie, as applied to claim 7, further in view of Leavitt et al. (US 6,352,682B1).

Dake et al. do not disclose that the radioactive source 14 is immobilized in a polymeric material that is selected from the group of elastomers, gels etc.

Leavitt et al. teach a polymer depot or radioactive source wherein a radioactive material is immobilized in a polymeric material that can be in the form of a gel (col. 1, lines 49-51, col. 2, lines 39-43, col. 3, lines 44-48 and col. 4, line 52) as a source of radiation.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of the catheter body 12 of the Dake et al.-Liprie device wherein the radioactive source is immobilized in a polymeric material in the form of a gel as a source of radiation as taught by Leavitt et al.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Liprie, as applied to claim 7, further in view of Carden, Jr. (US 5,405,309).

See discussion for claim 6.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of

body 12 of the Dake et al.-Liprie device wherein the radioactive source is carrier-free palladium-103 as taught by Carden, Jr. for enhanced safety.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Liprie, further in view of Hess.

Dake et al. do not disclose a retractable sheath. It is well known that radiation sources must be handled carefully to prevent radiation exposure (see Liprie, col. 7, lines 41-55).

Hess teaches a device 10 for radiation treatment with balloon 26 and radioactive elements 38 thereto (col. 3, lines 41-45, Figure 2 and Figure 4) wherein when balloon 36 is expanded in the vicinity of the lesion or treatment site, the radioactive source 38 is forced into contact with the treatment site. Further, Hess teaches an embodiment of device 10 including a retractable sheath (wire wound for radiation containment or shielding) or shield 24 that can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site such that a window cut-out 32 in radiation source 30 is opened to expose the treatment site to a radiation dose (col. 3, lines 26-40).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath in the catheter 10 of Dake et al. as modified by Liprie for radiation containment or shielding as taught by Hess.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Liprie in view of Hess and further in view of Leavitt et al.

Leavitt et al. teach a polymer depot or radioactive source wherein a radioactive material is immobilized in a polymeric material that can be in the form of a gel (col. 1, lines 49-51, col. 2, lines 39-43, col. 3, lines 44-48 and col. 4, line 52) as a source of radiation.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of the body of the Dake et al.-Liprie-Hess device wherein the radioactive source is immobilized in a polymeric material in the form of a gel as a source of radiation as taught by Leavitt et al.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Liprie in view of Hess, as applied to claim 15, further in view of Carden, Jr.

See discussion for claim 6.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of the catheter body 12 of the Dake et al-Liprie-Hess device wherein the radioactive source is carrier-free palladium-103 as taught by Carden, Jr. for enhanced safety.

Claims 21, 22, 23, 24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Mawad (US 5,498,227).

Dake et al. teach a hollow catheter or carrier 12 with a proximal segment 18 and a distal radioactive segment 30 or "substrate" containing a radioactive source 14 providing radiation of about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 of carrier 12 (col. 4, lines 17-23 and lines 34-36, and col. 5, lines 62-68 and col. 6, lines 1-5).

Dake et al. do not disclose that distal segment 30 is releasably attached to proximal segment 18.

Mawad discloses a radiotherapy device wherein an attachment or "distal segment" 1 with a substrate (10, 12) having a radioactive source 10 designed and adapted to deliver intended dosage of radiation to body tissues (col. 3, lines 27-40) is releasably attached to a delivery wire or "proximal segment" 14 for delivery of attachment 1 to a treatment site (col. 2, lines 42-48 and lines 53-57 and Figure 2).

Releasable attachment utilizing threads, snap-fit or press-fit are well known in the art.

Accordingly it would have been obvious to one of ordinary skill in the art to have releasably attached radioactive segment 30 to proximal segment 18 in the Dake et al. device so that radioactive segment 30 can be delivered to a treatment site as taught by Mawad. Further, it would have been obvious to have provided a radioactive source in the Dake et al.-Mawad device to deliver 0.5 microcuries to 300 curies per centimeter length of the "tubular" substrate in which the radioactive source is positioned since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 22-24, see discussion for claims 1, 3 and 4.

Regarding claims 26 and 27, Dake et al. disclose pellets 14 housed in carrier 12 (col. 5, lines 19-24).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Mawad further in view of Hess.

Dake et al. do not disclose that radioactive segment 30 has an expandable portion wherein the radioactive source 14 is bonded to the surface of the expandable portion.

Hess teaches a device 34 having a balloon or "distal expandable radioactive segment" 36 (col. 3, lines 41-47 and Figure 2) with radioactive elements 38 so that expansion of the balloon forces radioactive elements 38 into contact with a lesion or "treatment site" (col. 3, lines 56-59 and Figure 4).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a distal radioactive segment 30 in the Dake et al.-Mawad device wherein the distal radioactive segment 30 is an expandable segment with the radioactive source bonded to its surface to enable contact of the radioactive source with a treatment site as taught by Hess.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Mawad further in view of Leavitt et al.

Dake et al. do not disclose a radioactive source immobilized in polymeric material.

Leavitt et al. teach a radioactive source such a polymer depot wherein radioactive ions are immobilized in a polymeric gel.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a polymer depot as a radioactive source for immobilization of radioactive ions in a polymeric gel as taught by Leavitt et al.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Mawad (US 5,498,227) further in view of Carden, Jr.

Dake et al. do not disclose that the radioactive material can be made of carrier-free palladium 103.

Carden, Jr. teaches carrier-free palladium 103 (Pd-103) as a safe radiation source for therapeutic purposes (col. 1, lines 40-41, col. 4 and col. 5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free palladium-103 as the radioactive material in the Dake et al.-Mawad device for enhanced safety as taught by Carden Jr.

Claims 31, 33, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess in view of Fagan et al. (US 5,645,529).

Hess discloses a device 10 with a balloon or expandable housing 36, a radiation source or radioactive elements 38 attached to the outer surface of housing 36 and a mount or "guidewire port" 28 for mounting device 10 on a guidewire 26 (Figure 1 and col. 3, lines 26-47 and lines 56-59).

Hess does not disclose a multi-lobed balloon catheter.

Fagan et al. teach a multi-lobed balloon catheter having a plurality of lobes or chambers 61 and a shaft opening 63 wherein some of the lumens 62 may be open and can be used to perfuse blood therethrough to minimize trauma that would be otherwise caused by the balloon fully occluding the artery when the balloon is inflated (Figures 6a-6d, Figure 7, col. 6, lines 4-9 and lines 51-65). Fagan et al. also teach that the multi-lobed balloons 6a, 6b, 6c, 6d and 7 can be inflated simultaneously necessitating connection to a common fluid pathway for inflation of the balloons.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to provided a multi-lobed balloon in the device 10 of Hess, as taught by Fagan et al. to prevent occlusion of the vessel in which device 10 is inserted.

Regarding claim 34, Hess discloses a sheath 50 to provide shielding for the radioactive dose means 54 (Figure 5, col. 4, lines 15-23). Hess does not disclose a radiation stable outer coating.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a radiation stable outer coating instead of a sheath since the

examiner takes Official Notice of the equivalence of a sheath and a coating for their use in the art for the purpose of covering a surface and the selection of any of these known equivalents for the purpose of covering device 10 of Hess would be within the level of ordinary skill in the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Krasnicki et al. (US 4,676,229): Attachment of a material to the outer surface of a tubular substrate utilizing an adhesive having sufficient bond strength (col. 3, lines 49-53).

Bell (US 6,183,440): Releasable attachment means include threads, snap-fit or press-fit types of attachment (col. 6, lines 60-62).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR
February 20, 2003

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